

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUST LITIGATION</b>	<b>MDL 2724 16-MD-2724</b>
<b>THIS DOCUMENT RELATES TO:</b>	<b>HON. CYNTHIA M. RUGE</b>
<b><i>CERTAIN END-PAYER PLAINTIFFS ACTIONS</i></b>	
<i>In Re: Amitriptyline Cases</i>	<b>16-AM-27242</b>
<i>In Re: Benazepril HCTZ Cases</i>	<b>16-BZ-27242</b>
<i>In Re: Desonide Cases</i>	<b>16-DS-27242</b>
<i>In Re: Fluocinonide Cases</i>	<b>16-FL-27242</b>
<i>In Re: Levothyroxine Cases</i>	<b>16-LV-27242</b>
<i>In Re: Lidocaine-Prilocaine Cases</i>	<b>16-LD-27242</b>
<i>In Re: Pravastatin Cases</i>	<b>16-PV-27242</b>
<i>1199seiu National Benefit Fund v. Actavis Holdco U.S., Inc.</i>	<b>18-cv-2401</b>
<i>1199seiu National Benefit Fund v. Actavis Holdco U.S., Inc.</i>	<b>19-cv-6011</b>
<b><i>CERTAIN INDIRECT RESELLER PLAINTIFFS ACTIONS</i></b>	
<i>In Re: Amitriptyline Cases</i>	<b>16-AM-27243</b>
<i>In Re: Benazepril-HCTZ Cases</i>	<b>16-BZ-27243</b>
<i>In Re: Clobetasol Cases</i>	<b>16-CB-27243</b>
<i>In Re: Clomipramine Cases</i>	<b>16-CM-27243</b>
<i>In Re: Desonide Cases</i>	<b>16-DS-27243</b>
<i>In Re: Levothyroxine Cases</i>	<b>16-LV-27243</b>
<i>In Re: Lidocaine-Prilocaine Cases</i>	<b>16-LD-27243</b>
<i>In Re: Pravastatin Cases</i>	<b>16-PV-27243</b>
<i>West Val Pharmacy v. Actavis Holdco U.S., Inc.</i>	<b>18-cv-2533</b>
<i>Reliable Pharmacy v. Actavis Holdco U.S., Inc.</i>	<b>19-cv-6044</b>
<i>Reliable Pharmacy v. Actavis Holdco U.S., Inc.</i>	<b>20-cv-6291</b>
<b><i>CERTAIN DIRECT ACTION PLAINTIFFS ACTIONS</i></b>	
<i>The Kroger Co. v. Actavis Holdco U.S. Inc.</i>	<b>18-cv-284</b>
<i>Humana Inc. v. Actavis Elizabeth, LLC</i>	<b>18-cv-3299</b>
<i>United Healthcare Services, Inc. v. Actavis Holdco U.S., Inc.</i>	<b>19-cv-629</b>
<i>Humana Inc. v. Actavis Elizabeth LLC</i>	<b>19-cv-4862</b>
<i>United Healthcare Services, Inc. v. Teva Pharmaceuticals USA, Inc.</i>	<b>19-cv-5042</b>
<i>Health Care Service Corp. v. Actavis Elizabeth, LLC</i>	<b>19-cv-5819</b>
<i>MSP Recovery Claims, Series LLC v. Actavis Elizabeth, LLC</i>	<b>20-cv-231</b>
<i>Molina Healthcare, Inc. v. Actavis Elizabeth, LLC</i>	<b>20-cv-695</b>

<i>Cigna Corp. v. Actavis Holdco US, Inc.</i>	<b>20-cv-2711</b>
<i>Rite Aid Corporation v. Actavis Holdco U.S., Inc.</i>	<b>20-cv-3367</b>
<i>J M Smith Corporation v. Actavis Holdco U.S. Inc.</i>	<b>20-cv-4370</b>
<i>Walgreen Company v. Actavis Holdco U.S., Inc.</i>	<b>20-cv-6258</b>
<i>Winn-Dixie Stores, Inc. v. Actavis Holdco U.S.</i>	<b>20-cv-6290</b>
<i>Humana Inc. v. Actavis Elizabeth, LLC, et al.</i>	<b>20-cv-6303</b>
<i>CVS Pharmacy, Inc. v. Actavis Elizabeth, LLC</i>	<b>20-cv-6310</b>
<i>United HealthCare Services, Inc. v. Sandoz, Inc.</i>	<b>20-cv-6557</b>
<i>Providence St. Joseph Health v. Actavis Holdco U.S., Inc.</i>	<b>23-cv-3636</b>

***CERTAIN DIRECT ACTION PLAINTIFFS (SELF-INSURED)***

<i>County of Nassau et al. v. Actavis Holdco U.S., Inc.</i>	<b>20-cv-65</b>
<i>County of Suffolk v. Actavis Holdco US, Inc.</i>	<b>20-cv-4893</b>
<i>County of Albany v. Actavis Holdco U.S., Inc.</i>	<b>21-cv-1875</b>
<i>County of Westchester v. Actavis Holdco U.S., Inc.</i>	<b>21-cv-4474</b>

**MEMORANDUM OPINION**

**Rufe, J.**

**March 5, 2025**

Plaintiffs in the above-captioned cases have filed motions for leave to amend and supplement their Complaints to add two new Defendants, Novartis AG and Sandoz AG.<sup>1</sup> The proposed amendments stem from a corporate transaction in which Novartis AG, then the parent of existing Defendant Sandoz Inc., launched Sandoz Group AG as an independent publicly traded company. Plaintiffs now seek to allege veil-piercing or direct liability theories against Novartis AG and Sandoz AG, to include allegations as to the intermingling of operations of Sandoz Inc. as well as allegations that recent transactions undermine the ability of Sandoz Inc. to satisfy any judgment in the MDL.<sup>2</sup>

<sup>1</sup> The motion has been withdrawn as to the End-Payer Plaintiffs' *Pravastatin* action, 16-PV-27242. See MDL Doc. No. 3247.

<sup>2</sup> Plaintiffs have not sought to amend and supplement the initial bellwether cases.

## I. LEGAL STANDARDS

Resolution of the motions turns on several Federal Rules of Civil Procedure. Under Rule 15, leave to amend should be “freely give[n] when justice so requires,”<sup>3</sup> and denial “is justified only on the grounds of bad faith, undue delay, prejudice, or futility.”<sup>4</sup> “[T]he burden is generally on the non-moving party to demonstrate why leave to amend should not be granted.”<sup>5</sup> The decision whether to grant leave to amend under Rule 15(a)(2) is within the “sound discretion” of the Court.<sup>6</sup>

Allegations concerning events that occurred after a complaint was filed are governed by Rule 15(d), which provides that “[o]n motion and reasonable notice, the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented.”<sup>7</sup> “Because it refers to events that occurred after the original pleading was filed, a supplemental pleading differs from an amendment, which covers matters that occurred before the filing of the original pleading but were overlooked at the time.”<sup>8</sup> “The standards

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<sup>3</sup> Fed. Rule Civ. P. 15(a)(2).

<sup>4</sup> *Alston v. Parker*, 363 F.3d 229, 236 (3d Cir. 2004) (citation omitted).

<sup>5</sup> *Rizzo v. PPL Serv. Corp.*, No. 03-5779, 2005 WL 1397217, at \*3 (E.D. Pa. June 10, 2005) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

<sup>6</sup> *In re Allergan ERISA Litig.*, 975 F.3d 348, 356 n. 13 (3d Cir. 2020) (quoting *Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 272 (3d Cir. 2001)).

<sup>7</sup> Fed. R. Civ. P. 15(d).

<sup>8</sup> *Owens-Illinois, Inc. v. Lake Shore Land Co.*, 610 F.2d 1185, 1188 (3d Cir. 1979).

for amendment and supplementation are similar, but they do not conform exactly as more lenience is afforded to amendment.”<sup>9</sup>

“By contrast, where a party seeks to amend its pleadings after a deadline set by court order, the decision whether to allow the amendment is controlled by Rule 16(b).”<sup>10</sup> “Under Rule 16(b), the party seeking the amendment is effectively asking the court not only for leave to amend its pleadings, but also the scheduling order. Because the party’s request now implicates the effective administration of justice, the party must show good cause in order to procure the court’s consent.”<sup>11</sup>

## II. DISCUSSION

### A. The Proposed Amendments and the Parties’ Arguments

Plaintiffs argue that the proposed amended and supplemented complaints stem from a corporate transaction in Switzerland. Novartis AG announced the intention to spin-off Sandoz AG on August 25, 2022; a prospectus was issued on August 18, 2023; the transaction was completed on October 4, 2023. Plaintiffs also contend that they learned the relevant facts surrounding the relationship between Novartis AG and Sandoz Inc. through depositions conducted in 2023.

Defendants argue that none of the proposed amendments challenge the legality of the 2023 transaction, but that Plaintiffs instead allege veil-piercing and direct-liability theories based on the relationship between Novartis AG and Sandoz Inc. during the period of alleged

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<sup>9</sup> *Lutter v. JNESO*, 86 F.4th 111, 125 n.13 (3d Cir. 2023).

<sup>10</sup> *Price v. Trans Union, LLC*, 737 F. Supp. 2d 276, 279 (E.D. Pa. 2010).

<sup>11</sup> *Id.*; see also *Dimensional Commc’ns, Inc. v. OZ Optics, Ltd.*, 148 F. App’x 82, 85 (3d Cir. 2005) (affirming district court’s decision denying leave to amend for failure to comply with Rule 16’s “good cause” standard); *E. Mins. & Chems. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000) (similar).

price fixing from 2009 to 2016. Defendants further argue that the proposed claims are based on documents that were produced to Plaintiffs years ago. Finally, Defendants argue that the proposed amendments would seriously prejudice Defendants and disrupt the MDL process; including delays inherent to the need to effect international service under the Hague Convention and the likelihood of motions to dismiss.

### **B. Cases Subject to a Rule 16 Scheduling Order**

Cases filed before November 20, 2018, are subject to Pretrial Order No. 61 (“PTO 61”), which set a deadline of December 21, 2018, for “[a]ny amendment to any currently outstanding complaint” except in certain circumstances not applicable here or “as permitted by the Federal Rules of Civil Procedure or Court Order.”<sup>12</sup> Pretrial Order No. 153 (“PTO 153”) established a deadline of December 15, 2020 for amendments and motions for leave to amend in cases filed or amended between September 1, 2019 and July 10, 2020.<sup>13</sup> The Court intended PTOs 61 and 153 to set firm deadlines for motions to amend as well as other pretrial deadlines for the included cases. Therefore, PTOs 61 and 153 are Rule 16 scheduling orders and Plaintiffs in the affected cases must meet the “good cause” standard before the Court “considers whether the party also meets Rule 15(a)’s more liberal standard” for amendment.<sup>14</sup>

For those cases subject to PTOs 61 and 153, the Court concludes that good cause has not been shown. “Good cause” under Rule 16(b) focuses on the diligence of the party

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<sup>12</sup> MDL Doc. No. 775. PTO 61 included additional language allowing amendments that are not applicable here. The Court does not find that PTO 79, which was in the context of certain specific circumstances, applies here.

<sup>13</sup> MDL Doc. No. 1648.

<sup>14</sup> *Premier Comp Solutions, LLC v. UPMC*, 970 F.3d 316, 319 (3d Cir. 2020).

seeking the modification of the scheduling order.”<sup>15</sup> “Thus, if the party was not diligent, there is no ‘good cause’ for modifying the scheduling order and allowing the party to file a motion to amend its pleading.”<sup>16</sup> Defendants have shown that information related to the newly-raised claims as to the relationship between Novartis AG and Sandoz Inc. was contained in documents produced years ago. Even if the transaction could be considered a basis for seeking amendment, the first motions to amend and supplement were not filed until January 2024, despite knowing about the pending transaction for much longer. Plaintiffs could have filed the motions earlier—some sought injunctive relief (later withdrawn) in September 2023 relating to the spin-off before it was even completed.

The parties were aware of the deadlines established by the Court’s scheduling orders. Being subject to those deadlines placed a burden on Plaintiffs in those cases to act with diligence in seeking to amend, particularly considering that these deadlines were established after substantial discussion over a period of months. Given the circumstances of the MDL, the Court concludes that Plaintiffs failed to act with the diligence required to satisfy good cause. The motions will be denied as to the cases subject to PTOs 61 and 153.<sup>17</sup>

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<sup>15</sup> *Hildebrand v. Dentsply Int’l, Inc.*, 264 F.R.D. 192, 198 (E.D. Pa. 2010).

<sup>16</sup> *Price*, 737 F. Supp. 2d at 279 (internal quotation marks omitted).

<sup>17</sup> The Court also notes that with regard to the cases filed by the EPPs, those Plaintiffs recently reached a settlement of all their cases with Sandoz, Inc. (and Fougera Pharmaceuticals) in an amount up to \$275 million; the Court has preliminarily approved the settlement after having previously granted final approval of a \$265 million settlement with the direct-purchaser class. Thus, as to the EPPs the proposed amendment is likely moot; to the extent it is not, the settlement undercuts the premise of the argument that Sandoz Inc. has been stripped of assets necessary to compensate Plaintiffs.

### C. Cases Subject Only to Rules 15 and 20

As discussed above, amendment under the liberal standard of Rule 15 should be granted unless there is a finding of bad faith, undue delay, prejudice, or futility. Here, there is no basis for concluding that Plaintiffs have acted in bad faith. The Court will not consider whether the claims will survive potential motions to dismiss as the Third Circuit has emphasized that Rule 15 “‘embodie[s]’ a ‘clear preference . . . for merits-based decision making.’”<sup>18</sup> Where a proposed amendment includes new claims and the futility of those claims is not clear, “the better course is to liberally allow amendments that state a colorable claim and defer judgment as to whether they survive a motion to dismiss for failure to state a claim until such time when that motion is raised.”<sup>19</sup>

For the Court to deny amendment, then, Defendants must show either prejudice or undue delay. The need for “additional discovery, cost, and preparation [for the non-moving party] to defend against new facts or new theories” may contribute to a finding that amendment would be prejudicial.<sup>20</sup> Although the Third Circuit has “expressed a preference for allowance of the amendment, so long as the opposing party is not prejudiced,”<sup>21</sup> a “finding of undue delay, on its own, suffices” as a basis to deny a motion to amend<sup>22</sup> where the delay has placed “an unwarranted burden on the court.”<sup>23</sup>

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<sup>18</sup> *Se. Pa. Transp. Auth. v. Orrstown Fin. Servs., Inc.*, 12 F.4th 337, 345 (3d Cir. 2021) (quoting *T Mobile Ne. LLC v. City of Wilmington*, 913 F.3d 311, 328 (3d Cir. 2019)).

<sup>19</sup> *Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 736 (D. Del. 2002).

<sup>20</sup> *Cureton*, 252 F.3d at 273.

<sup>21</sup> *DLJ Mortg. Cap., Inc. v. Sheridan*, 975 F.3d 358, 369 (3d Cir. 2020).

<sup>22</sup> *Spartan Concrete Prods., LLC v. Argos USVI, Corp.*, 929 F.3d 107, 117 (3d Cir. 2019).

<sup>23</sup> *Cureton*, 252 F.3d at 273 .

As to those cases that are not subject to the Court's scheduling orders, the Court determines that Defendants have not shown a basis for denying amendment. As discussed above, Plaintiffs could have moved with more dispatch in seeking amendment. However, the Court does not find that amendment will place an undue burden on the Court in the management of the MDL as to these newer cases, which have not been subject to court-ordered deadlines governing amendment.

Nor is the Court persuaded that amendment would create substantial prejudice to Defendants. The Court recognizes that there may be delays from the filing of motions to dismiss, and that some additional discovery will be necessary, but these are not insurmountable obstacles. The Court expects that the parties will cooperate to complete the additional discovery relevant to the amendments promptly. The Court will permit additional discovery as needed to protect the interests of the newly-added Defendants, but notes that it will not be necessary to reopen all previous discovery given that Sandoz Inc. has participated in the discovery process to date and would have advanced the same interests as Novartis AG and Sandoz AG. To facilitate the additional discovery process, the Court will call upon the expertise of the Special Masters to resolve any disputes expeditiously.

Finally, the Court concludes that addition of these Defendants satisfies Rule 20(a)(2) as Plaintiffs allege that Novartis AG, Sandoz AG, and Sandoz Inc. are jointly and severally liable and that their actions were intertwined. In this regard, the Court also notes that Novartis AG and Sandoz AG are already named as Defendants in the MDL, although that is not a consideration for the Court with regard to allowing amendment.<sup>24</sup>

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<sup>24</sup> See, e.g., *American Airlines, Inc. v. Actavis Holdco U.S., Inc.*, No. 24-1430 (E.D. Pa. filed Apr. 4, 2024).

### **III. CONCLUSION**

For the reasons stated above, the Court will deny the motions to amend as to those cases subject to PTOs 61 and 153, and will grant the motions as to the remaining cases. An order will be entered.